NIH POLICY MANUAL

54205 - ROLE OF THE PI ON RESEARCH PROJECTS SUPPORTED BY NIH

Issuing Office: OER 301-496-5967
Release Date: 11/01/91

A. Purpose:

This chapter describes the roles and responsibilities of principal investigators on research projects supported by NIH financial assistance awards, that is, grants and cooperative agreements. (The word "grant," as used throughout this chapter, also includes "cooperative agreement.")

B. Background:

The Code of Federal Regulations, Title 42, Part 52 (GRANTS FOR RESEARCH PROJECTS), defines a principal investigator as "a single individual designated by the grantee in the grant application and approved by the Secretary, who is responsible for the scientific and technical direction of the project." Part 52 provides that the name and qualifications of the principal investigator must be included in grant applications and, from a postaward perspective, the regulation describes the permissible changes that a principal investigator may make in carrying out the approved project. Finally, Part 52 identifies 45 CFR Part 74 (ADMINISTRATION OF GRANTS) as a Department-wide (DHHS) regulation that applies to NIH research project grants. The Public Health Service (PHS) Grants Policy Statement represents yet another important source of policy information governing the award and administration of NIH research project grants. In sum, each of the formally- recognized policy documents cited above (and other materials listed under "References," below) have contributed to the guidance in this chapter. In addition, the chapter reflects procedural information and expressions of policy from sources such as grant application instructions, information in the NIH Guide for Grants and Contracts, and actual case- histories involving issues associated with the role of a principal investigator.

C. Applicability:

This chapter summarizes the referenced policy and procedures which apply to awards for research project grant support. The original sources must be referred to for additional detail or procedures. Only policy implemented in the CFR and the PHS Grants Policy Statement apply specific requirements on applicants and recipients.

D. References:

1. Code of Federal Regulations, Title 42, Part 52, Grants for Research Projects.
2. Code of Federal Regulations, Title 45, Part 74, Administration of Grants.
3. Code of Federal Regulations, Title 45, Part 76, Debarment and Suspension.
4. Code of Federal Regulations, Title 37, Part 401, Rights to Inventions Made by Nonprofit Organizations and Small Business Firms Under Government Grants, Contracts, and Cooperative Agreements.
5. Code of Federal Regulations, Title 45, Part 8, Inventions Resulting from Research Grants, Fellowship Awards, and Contracts for Research.
6. Code of Federal Regulations, Title 45, Part 79, Program Fraud Civil Remedies.
7. PHS Grants Policy Statement.
8. PHS Grants Administration Manual Part 109, Overdue Reports--Discretionary Grants.
9. PHS Grants Administration Manual Part 129, Grant Suspension and Termination.
10. PHS Grants Administration Manual Part 131, Change of Grantee Institution.
11. PHS Grants Administration Manual Part 145, PHS Prior Approval Requirements.
12. PHS Grants Administration Manual Part 201, Review and Direction of the Research Effort Under Research Grants.
13. NIH Manual Chapter 4201, Release of Information on Research and Training Grants, Awards, and Cooperative Agreements.
14. NIH Manual Chapter 4204/6003-1, NIH Intramural Scientists as Principal Investigators on Grant Applications and Contract Proposals.
15. NIH Manual Chapter 4509, Personal Data Page of Form PHS-398 Grant Application.
16. NIH Manual Chapter 4510, Referral and Initial Review of (Grant) Applications.
17. NIH Manual Chapter 4512, Summary Statements.
18. NIH Manual Chapter 5201, Change of Grantee Institution.
19. NIH Manual Chapter 5806, Overdue Reports-Discretionary Grants.
20. NIH Manual Chapter 1820, Selection of Extramural Award Instrument - Grant, Cooperative Agreement, or Contract.

21. NIH Manual Chapter 4815, Implementation of Cooperative Agreements - Initiation, Review, Award and Administration.

E. Definitions:

1. Principal Investigator Federal regulations define a principal investigator (PI) as "a single individual designated by the grantee in the grant application and approved by the Secretary, HHS, who is responsible for the scientific and technical direction of the project." (See 42 CFR Part 52.) The concept of co-investigator is not formally recognized.

2. Grantee The organization to which a grant is awarded and which is responsible and accountable to NIH for the ON RESEARCH PROJECTS SUPPORTED BY NIH use of the funds provided and for performance of the grant-supported project. In unusual circumstances, an individual may be a grantee.

F. Policies/Procedures:

1. Overall Responsibilities

   Consistent with the regulatory definition of "principal investigator" (PI) (as provided above), NIH considers that individual to be the primary guiding force behind the hypothesis, development, and "hands-on" execution of the research activity and supervision of scientific and technical staff. In accepting this role, the PI also undertakes a fiscal management obligation to the grantee (as defined above) to expend grant funds for the purposes set forth in the application and the Notice of Grant Award in accordance with applicable laws and regulations. (See 45 CFR Part 79)

2. Application Requirements

   a. Identification In accordance with the appropriate instructions, applications for research project grant support must reflect the name and qualifications of the PI, as well as the level of effort to be devoted to the project.

   b. Other Support Grant application instructions (Forms PHS 398 and 2590) require a listing of the PI's "other sources of research support," both active and pending. To prevent the possibility of duplicate (overlap) funding, it is the PI's responsibility to update this information. If there are changes in the information after submission of a competing application, the PI must notify the Scientific Review Administrator (SRA) of the initial review group before the review. If changes occur after the review of a competing application, or at any other time in the life of a project, the principal investigator must notify the appropriate Grants Management Officer (GMO) of the awarding component.

   c. Personal Data The Personal Data form, which is part of the competing application package, asks the age, sex, race/ethnic origin, and social security number of the PI. Submitting the form is optional and the data obtained is used

only for statistical analysis. If the form is submitted, it is separated from the application prior to review. The review of the application will not be affected by either the submission of the form or the form's content. (See NIH Manual Chapter 4509.)

d. Appointments The PI must have a formal appointment with the applicant organization, which is characterized by an official relationship between the organization and the individual. Such a relationship does not necessarily involve a salary or other form of remuneration. In all cases, however, the individual's official organizational relationship must entail sufficient opportunity and physical resources for the principal investigator to carry out his/her responsibilities for the overall scientific and technical direction of the projec and for the organization to provide administrative and financial oversight of the project. An investigator with a full-time 12-month appointment would be considered to have a commitment to the applicant organization of 100 percent of his/her total professional effort. If, on the other hand, an investigator (concurrently) has independent commitments or appointments with other organizations, his/her commitment to the applicant organization would be some portion of 100 percent. However, when concurrent (joint) appointments are, in fact, dependent upon each other, the joint appointment is considered to represent the individual's total professional effort. For example, a principal investigator with a university appointment may also have an appointment with an affiliated hospital and still appropriately consider his/her commitment to the university to be full time, as long as the university and the hospital are mutually responsible for the individual's total professional effort.

e. Department of Veterans Affairs (VA) Employees: Special Certification Academic institutions submitting applications on behalf of principal investigators who are also VA employees must certify that: (1) the individual is applying as part of a joint appointment that is specified by a formal Memorandum of Understanding (see next paragraph), and (2) there is no possibility of dual compensation (academic plus VA salary) for the same work, nor an actual or apparent conflict of interest regarding such work.

The Memorandum of Understanding must, at a minimum, specify: (1) the title of each appointment, (2) each functional responsibility (at both the academic institution and the VA) of the proposed principal investigator, and (3) the percentage of effort available for research. Staff may request evidence of a proper memorandum of understanding, but submission of said memorandum is not a routine requirement of the applicant. (See NIH Guide for Grants and Contracts.)

f. Non-U.S. Citizens The U.S. grantee organization shall determine, and the application should indicate, that the PI's visa will allow him/her to remain in the country a length of time sufficient to direct the project. NIH will not intercede in behalf of non-United States citizens who may be principal investigators (or otherwise participating in a project), and whose stay in the United States may

be limited by their visa status.

g. Signature To be valid and acceptable for review, an application must have been signed by the proposed PI. By signing, the principal investigator agrees to accept fiscal responsibility, as well as responsibility for the scientific conduct of the project, and to provide the required progress reports if a grant is awarded as a result of the application. "Per" signatures are not acceptable. (see Form PHS 398.)

3. Preaward Review Considerations of the Role of the PI

In instances during the peer review process where there may be questions concerning the extent of participation (percent effort) or the relationship of the PI to the project, the SRA of the initial review group (IRG) should, where possible, obtain a statement from the applicant organization, prior to the IRG meeting, regarding the primary responsibility for scientific and technical direction of the project. If the named PI's role is questionable, the SRA should guide the IRG to recommend deferral until clarification can be obtained. If the IRG determines that the named principal investigator will not be clearly responsible for the scientific and technical direction of the project, the project may not be recommended for further consideration.

If staff of the NIH awarding component, in reviewing an application or summary statement, is not satisfied that the named PI is appropriate or that the level of effort is sufficient, they must clarify the situation even if the timing of such clarification requires a delay in processing the award. No award may be made by the NIH awarding component unless the role and level of effort of the PI is defined clearly and to the satisfaction of the awarding component.

For cooperative agreement awards, the PI has prior knowledge of and agrees to special Terms of Award which define the role of the PI and the "substantial programmatic involvement" of NIH staff in the project, and include arbitration mechanisms covering disagreements over programmatic decisions on scientific-technical matters. These terms are in addition to other grant administration policies. (See NIH Manual Chapters 1820 and 4815).

4. Release of Information

a. Privacy Act The Privacy Act of 1974 (Public Law 93-579), and associated regulations at 45 CFR Part 5b, provide certain safeguards for individuals (including principal investigators) against invasions of personal privacy. These safeguards include (1) the right of individuals to determine what records pertaining to him/her are collected, maintained, used or disseminated by NIH, and (2) the right of individuals to have access to such records and to correct, amend, or request deletion of information in their records that is inaccurate, irrelevant, or outdated. (See PHS Grants Policy Statement and PHS Grants Administration Manual Chapter 7, Part 707)

b. Freedom of Information The Freedom of Information Act (Public Law 90-23), and associated regulations at 45 CFR Part 5, require the release by NIH of certain grant documents and records requested by members of the public. The applicant organization and the PIs are to be notified by the NIH awarding component when a Freedom of Information request is received and to whom the documents will be released. The PI will be given an opportunity to identify potentially patentable or otherwise intrinsically valuable information that should not be disclosed. (See PHS Grants Policy Statement and PHS Grants Administration Manual Chapter 2, Part 202)

5. Postaward Issue Considerations of the Role of the PI

a. Reporting Accomplishments It is incumbent upon the PI to make results and accomplishments of his/her research available to the public in a timely manner. NIH prior approval is not required for publishing such results. Although responsibility for the direction or sponsorship of the grant research activity should not be ascribed to NIH, the PI shall place an acknowledgement of NIH grant support on any publication written or published with such support and, if feasible, on any publication reporting the results of, or describing, a grant-supported activity. An acknowledgment may be to the effect that "this publication was made possible by a grant from..." or "the project described was supported by a grant from...."

If the grantee institution and/or PI wish to have NIH join in a simultaneous news release announcing the results of a project, the action is to be coordinated with the NIH awarding component.

Two reprints of publications resulting from work on an NIH-supported grant activity must be submitted by the PI to the NIH awarding component. (See PHS Grants Policy Statement.)

b. Changes in Research Objectives It is expected and, indeed encouraged, that recipients of an NIH research grant will continually adapt their methods and technical approaches as necessary to better achieve their research goals. Minor changes in allocation of personnel or rebudgeting that will further the work are acceptable. However, proposed changes in the scope or objectives of the research must be discussed with the NIH awarding component to determine if they are appropriate with respect to the project's original goals and scope. A memo to the record will be filed to document changes in work scope. Significant changes in the goals of a project may require submission of a competitive application either for a supplemental award or for an independent grant. (See PHS Grants Policy Statement.)

c. Change in Status or Absence of Principal Investigator Postaward changes in the level of participation in the approved project by the PI are generally acceptable. However, a significant decrease in the level of effort from that level

originally proposed, should be submitted in advance for approval by the NIH awarding component. Expressed in terms of a ratio, a proposed decrease in effort of 1/5 from the level originally proposed, is considered "significant." For example, if the PI is currently devoting 40% effort to the project, a reduction of 20% (1/5) would be reflected as a 32% effort (i.e., any reduction equal to or greater than 8 percentage points from 40%).

When the project will be without the active direction of its PI for a continuous period of three or more months, the NIH awarding component must be notified and plans for the continuing conduct of the research project must be approved.

While absent from the main performance site of the project for three or more months, the PI may propose to direct the project via periodic visits and frequently scheduled communications. If such arrangements are deemed to be impractical by the GMO, the grantee institution must propose an interim PI for approval by the NIH awarding component.

If a PI withdraws from a project at any time prior to its completion, the grantee institution may submit to the NIH awarding component plans for continuation of the research under a replacement PI. If those plans are unacceptable to NIH awarding component, the grant must be terminated. (See PHS Grants Policy Statement and PHS Grants Administration Manual Part 129.)

d. Sabbatical Leave A PI's salary may be charged directly to a project for services rendered the project by that individual while he/she is on sabbatical leave, provided that the salary is proportional to the service rendered and is paid according to established institutional policies applicable to all employees regardless of the source of funds. Sabbatical leave paid by an individual's employer, in combination with other compensation (e.g., partial salary from an NIH grant), may not exceed 100 percent of an individual's regular salary from his/her institution. Plans for grant-supported effort of the PI during sabbatical leave, as well as plans for the continuation of the research project in his/her own laboratory, must be approved in advance by the NIH awarding component. Additional funds will not be awarded to support an interim PI if the originally named PI is away for more than three months. (See PHS Grants Policy Statement.)

e. Change of Grantee Institution NIH Manual Chapter 5201 describes the policies and procedures associated with the following changes:

(1) When a PI departs from the grantee institution and the institution requests continuation of the project under the direction of another PI.

(2) When a PI departs from an institution and there is an NIH-approved, but not yet awarded (or activated) grant.

(3) When the PI departs from an institution and requests that the project

be supported at another institution.

f. Requesting NIH Approvals The PHS Grants Policy Statement and Part 145 of the PHS Grants Administration Manual describe those postaward actions that require prior written approval of the awarding component. All such requests received by NIH awarding components must bear the signature of both the PI and an authorized institutional official of the grantee organization.

6. Reporting Requirements

a. Performance (Progress) Reports Well-written progress reports are central to an NIH awarding component's programmatic evaluation of a PI's research activity and an evaluation of the project's needs. They also serve several broader purposes by providing current information to NIH staff about scientific advances, aiding staff in planning future program goals, and assisting in the preparation of reports to Congress and others about the progress in those areas of scientific research.

Annual and final progress reports are submitted with all applications for competing continuation or noncompeting continuation support, in accordance with instructions accompanying the application forms. The original and two copies of a final progress report must be submitted to the NIH awarding component within 90 days after the expiration of the project. The final report should include, at a minimum, a summary statement of progress toward the achievement of the originally stated aims, a list of the results (positive or negative) considered significant, and a list of publications resulting from the project. Two copies of reprints of publications not previously submitted should accompany the report. (See Non-competing Continuation Application.)

b. Invention Reports All inventions made in the course of (or under) an NIH research grant shall be promptly and fully reported by the PI to the grantee, who will in turn disclose the invention to the Extramural Inventions Office, OER, NIH, Building 31, Room 5B41, Bethesda, MD 20892.

In addition to prompt invention reporting (above) and regular reporting (or certification) as part of the grant application process, the principal investigator and an official authorized to sign on behalf of the grantee organization must submit to the NIH awarding component a Final Invention Statement and Certification within 90 days following the expiration or termination of grant support. All inventions that were conceived or originally reduced to practice during the course of work under the project, from the original effective date of support through the date of expiration or termination, whether or not previously reported, shall be listed on the statement. (See NIH Manual Chapter 5806 regarding Overdue Reports.)

7. NIH Intramural Research Scientists

NIH Manual Chapter 4204/6003-1 sets forth conditions and procedures under which an NIH intramural research scientist, while still employed by NIH, may develop and submit grant applications to NIH or other agencies of the Federal government, naming that research scientist as the PI for proposed research or related projects which would commence after he/she terminates Federal employment. Those requirements apply specifically to NIH intramural research scientists who have no official duties or responsibilities with respect to the review, evaluation, advice, or recommendations on grant applications submitted to NIH, and who are not otherwise involved in NIH grant administration.

G. Effective Date:

This policy is effective on date of release.

H. Additional Information:

For further information on this chapter contact the Grants Policy Office, Office of Extramural Programs, Building 31, Room 5B50. Telephone: 496-5967.

I. Additional Copies:

Copies of this manual chapter can be obtained by sending Form NIH 414-5, "Request for Manual Chapter" to the Printing and Reproduction Branch (P&RB), DTS, Building 31, Room B4BN09.